

Randomised single blind patient controlled trial of VNUS closure compared with groin dissection and long saphenous vein (LSV) stripping for recurrent varicose veins

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 26/08/2008	Condition category Circulatory System	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0192119061

Study information

Scientific Title

Study objectives

To determine whether VNUS is as effective as groin re-exploration for recurrent varicose veins in association with a recurrently incompetent long saphenous vein (LSV). Assessment will be by Duplex scan at 6 weeks, 1 year and 5 years.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Cardiovascular: Recurrent varicose veins

Interventions

VNUS closure compared with groin dissection and long saphenous vein (LSV) stripping for recurrent varicose veins

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Operative time, visual analogue scales for pain and bruising, costs of procedure, recurrence rates.

Secondary outcome measures

Not provided at time of registration

Overall study start date

31/07/2002

Completion date

12/12/2004

Eligibility

Key inclusion criteria

Age 18-80

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

80 Years

Sex

Not Specified

Target number of participants

60

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

31/07/2002

Date of final enrolment

12/12/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Department of Vascular Surgery
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
<http://www.doh.gov.uk>

Funder(s)

Funder type
Government

Funder Name
Queen's Medical Centre University Hospital NHS Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2006		Yes	No